--39. The probe of claim 5, wherein said probe contains at least five contiguous nucleotides of said nucleotide sequence.--

--40. The primer of claim 8, wherein said primer contains at least five contiguous nucleotides of said nucleotide sequence.--

REMARKS

Claims 1, 2, 5, 7, 8, 10-27, 32, 34 and 36-40 are pending. Claims 9, 29, 31, 33 and 35 are canceled; claims 5, 8, 11, 18, 21-24, 32 and 34 are amended; and claims 36-40 are added herein.

The attached Appendix includes marked-up copies of each rewritten claim (37 C.F.R. §1.121(c)(1)(ii)).

It is respectfully submitted that the finality of the present Office Action is improper. In particular, the Office Action rejects claim 11 based on its dependence on claim 5. In addition, the Office Action rejects claims 18 and 19 based on their failure to state hybridization conditions. Neither of these two rejections are based on any amendment made by Applicants in the previous Amendment. Therefore, it is improper to make these rejections for the first time in a final Office Action. Thus, the finality of the present Office Action should be withdrawn and the present amendments should be entered.

In addition, it is respectfully submitted that entry of these amendments is proper under 37 C.F.R. §1.116. In particular, the amendments: (a) place the application in condition for allowance for the reasons discussed herein; (b) do not raise any new issues requiring further search and/or consideration, since the amendments amplify issues previously discussed throughout prosecution; (c) satisfy a requirement of form asserted in the previous Office Action; (d) do not add any claims without canceling a corresponding number of finally rejected claims; and (e) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are

made in response to arguments raised in the final rejection. Thus, entry of the amendments is respectfully requested.

Applicants appreciate the indication that the substitute paper and computer-readable copies of the sequence listing have been received. It is understood that the present Office Action was sent prior to the results of a new search based on this sequence listing, and that a Supplemental Office Action will be mailed to Applicants if any prior art references are uncovered during this search.

Claims 1, 2, 5, 7-27, 29 and 31-35 are rejected under 35 U.S.C. §112, second paragraph. Claims 29 and 31 have been canceled, rendering the rejection of these claims moot. With regard to the other claims rejected on this basis, Applicants respectfully traverse the rejection.

First, it is noted that the Office Action sets forth no basis for rejecting any of claims 1, 2, 5, 7-17, 25, 26, 32 and 33, nor does any of these claims depend from a claim for which any basis of rejection is set forth. Therefore, it is respectfully submitted that the rejection of at least these claims under 35 U.S.C. §112, second paragraph, should clearly be withdrawn.

Claim 11 has been amended in an effort to clarify the invention. In particular, claim 11 has been amended to more clearly recite that both the capture and the detection probe is in accordance with claim 5. Thus, the reagent of claim 11 comprises at least two probes, one of which being a capture probe and one of which being a detection probe, and both of these probes individually meet the limitations of claim 5 although the nucleotide sequence of each of these two probes is different from each other. It is respectfully submitted that this would be clearly understood by one of ordinary skill in the art.

Claims 21-24 are rejected based on the use of open claim language "comprising," the recitation of "one segment" and the recitation of "a second nucleotide sequence." Claims 21-24 have been amended to delete reference to the at least one segment and the second nucleotide sequence. In addition, it is respectfully submitted that the use of open claim

language "comprising" does not render the claims unclear. Instead, these claims are clearly directed to larger sequences that comprise the specifically claimed sequences. In particular, it is agreed that these claims currently read on genomic or chromosomal DNA from T. cruzi that comprise the claimed nucleic acid sequences. The fact that a claim may be broad does not make it indefinite under 35 U.S.C. §112, second paragraph. In the present case, one of ordinary skill in the art can clearly tell whether a nucleic acid is within the claim. That is, if it contains the claimed sequence, it is within the claim; otherwise, it is not.

With regard to claims 18, 19 and 27, it is respectfully submitted that these claims are not indefinite. In particular, these claims are directed to methods for the detection and/or identification of Trypanosoma cruzi in a biological sample that comprise exposing a biological sample to at least one probe. As correctly pointed out by the Examiner, if sufficiently low hybridization conditions are used, the process would not accurately detect or identify Trypanosoma cruzi. However, it is respectfully submitted that the use of such stringency conditions would not be encompassed by the present claim language since such conditions would not result in the detection and/or identification of Trypanosoma cruzi. That is, the use of such conditions would not result in a process for detecting and/or identifying Trypanosoma cruzi and would therefore not be within the present claims that specifically recite a process for detecting and/or identifying Trypanosoma cruzi.

Claims 1, 2, 5, 7-27 and 32-35 clearly recite the invention. Therefore, the rejection of these claims under 35 U.S.C. §112, second paragraph, should be reconsidered and withdrawn.

Claims 5 and 8 and claims dependent thereon are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. Claim 8 has been amended to recite that the primer contains no more than 30 nucleotides. With regard to claim 5 and the claims dependent thereon, Applicants respectfully traverse the rejection.

Claim 5 is directed to a probe containing no more than 100 nucleotides. Support for this limitation can be found in the present specification at, for example, page 15, lines 15-22,

which recites that the term probe refers, in particular, to a sequence having, for any succession of 5 to 100 continuous monomers, a particular homology with SEQ ID NO: 1. Thus, the inventors clearly envisioned probes containing 100 and fewer nucleotides.

Further support for this subject matter can be found at, for example, claim 6 as originally filed in this divisional application, which recites that the probe comprises 5 to 100 nucleotides. In addition, support can be found in the parent of the above-identified patent application, which was incorporated by reference at the time the present application was filed, at, for example, original claim 25, which recites that the probe comprises a sequence of 5 to 100 nucleotides.

The subject matter of claims 5 and 8 and the claims dependent thereon are clearly supported by the present application. Therefore, the new matter rejections of these claims should be reconsidered and withdrawn.

Claims 18-24, 27, 29 and 31-35 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enablement. Applicants respectfully traverse the rejection.

First, it is noted that claim 32 is dependent on claim 17, which is not rejected on this basis. Claim 32 merely further defines the invention by reciting that the primer described in claim 17 contains no more than 30 nucleotides. The specification clearly enables primers containing no more than 30 nucleotides. Thus, based on the fact that claim 17 is not rejected on this basis, it is respectfully submitted that claim 32 should also not be rejected on this basis.

Claims 18-20, 27 and 34 are directed to methods for detecting and/or identifying Trypanosoma cruzi in a biological sample. It is noted that skill in the relevant art is high. In particular, one of ordinary skill in the art is of sufficient skill to be able to select appropriate hybridization conditions in order to practice the methods of the present invention. In particular, detection and identification of nucleic acid based on a probe and primer is routine in the art. Once one of ordinary skill in the art is provided with a probe, as described in the

present application, which can be used for the detection and/or identification of particular nucleic acid, one of ordinary skill in the art would be able to easily select without undue experimentation hybridization conditions that could be used in order to do so. The Office Action provides no indication that this would not have been within the capabilities of one of ordinary skill in the art.

Claims 21-24 are directed to nucleic acid fragments. Claims 21-23 recites nucleic acid fragments having a degree of homology with a specifically recited sequence. In contrast, claim 24 is specifically directed to a nucleic acid fragment containing a nucleotide sequence that is identical or fully complementary to a particular sequence. Therefore, it is respectfully submitted that the basis for rejection set forth in the Office Action does not apply to claim 24.

With regard to claims 21-23, the claims have been amended to recite that the nucleotide sequence has at least 85% homology with a sequence that is identical or fully complementary to specifically defined segments of SEQ ID NO: 1 or the corresponding RNA sequence. It is respectfully submitted that one of ordinary skill in the art would know how to make and use such homologous sequences, such as as probes and primers.

Claims 18-24, 27, 32 and 34 are enabled by the present specification. Therefore, the enablement rejection of these claims should be reconsidered and withdrawn.

Claims 21-23 are rejected under 35 U.S.C. §112, second paragraph, as allegedly lacking written description. Applicants respectfully traverse the rejection.

As discussed above, claims 21-23 have been amended to recite that the nucleotide sequence has at least 85% homology with a sequence that is identical or fully complementary to specifically defined segments of SEQ ID NO: 1 or the corresponding RNA sequence. The specification clearly indicates that the inventors contemplated such homologous sequences. See the specification at page 15, lines 15-30. One of ordinary skill in the art certainly understands homology and could easily discern and construct sequences with the claimed level of homology.

As noted in the Office Action, adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. However, contrary to the statement of the Office Action, case law has not held that the sequence of a nucleic acid is itself required. Instead, as indicated in the Office Action, the Federal Circuit held that written description requires a kind of specificity usually achieved by means of the recitation of the sequence of the nucleotide that make up the DNA. University of California v. Ely Lilly & Co., 119 F.3d 1559, 1568-69, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (emphasis added). Specifically, citing Fiers v. Revel, 984 F.2d 1164, 1170, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), the University of California stated that an adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." 119 F.3d at 1566, 43 USPQ2d at 1404 (emphasis added). In the present case, the inventors have clearly provided a lot of structural information about the claimed sequences. In particular, the specification indicates that the sequence comprises a sequence having at least 85% homology with a specifically recited segment of SEQ ID NO: 1 or its corresponding RNA. Such a recitation is clearly a precise definition, not a mere wish or plan for obtaining the claimed chemical invention.

For at least these reasons, the present specification clearly provides written description for the subject matter of claims 21-23. Therefore, the written description rejection of these claims should be reconsidered and withdrawn.

Claims 36-40 have been added to further define the invention. Claims 36-38 are specifically directed to the subject matter that the Examiner indicates to have written description. Therefore, adding these claims should not create any new issue. In addition, all of these claims are allowable for at least the reasons discussed above.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Favorable consideration and prompt allowance are therefore respectfully requested.

Should the Examiner believe anything further would be desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

William P. Berridge
Registration No. 30,024

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WPB:MLM/jam

Attachment:
Appendix

Date: December 26, 2001

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION
Please grant any extension necessary for entry;
Charge any fee due to our Deposit Account No. 15-0461

APPENDIX

Changes to Claims:

Claims 9, 29, 31, 33 and 35 are canceled.

Claims 36-40 are added.

The following is a marked-up version of the amended claims:

5. (~~Twice~~ Three Times Amended) A probe for identifying Trypanosoma cruzi, said probe ~~comprising a segment of at least five contiguous nucleotides of a nucleic acid consisting~~having at least 85 % homology with a fragment of a nucleotide sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said probe contains no more than 100 nucleotides.

8. (Three Times Amended) A primer for amplifying a nucleotide sequence, said primer ~~comprising a segment of at least five contiguous nucleotides of a nucleic acid consisting~~ having at least 85% homology with a fragment of a nucleotide sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said primer contains at least 5 and no more than ~~100~~ 30 nucleotides.

11. (Twice Amended) A reagent for detecting or identifying Trypanosoma cruzi in a biological sample, said reagent comprising a capture probe and a detection probe, both in accordance with claim 5, wherein said capture probe and said detection probe have nucleotide sequences that are different from one another.

18. (Amended) A method for detection and/or identification of Trypanosoma cruzi in a biological sample, comprising exposing ~~to at least one probe according to claim 5~~ denatured DNA extracted from Trypanosoma cruzi or DNA obtained by reverse transcription

of RNA extracted from Trypanosoma cruzi to at least one probe according to claim 5; and detecting hybridization of said probe.

21. (Twice Amended) A synthetic or isolated nucleic acid fragment that comprises a nucleotide sequence having~~, for at least one segment of 30 contiguous nucleotides,~~ at least 85% homology with ~~a segment of 30 contiguous nucleotides of~~ a reference sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide ~~2207~~ 1825 of SEQ ID NO: 1 or the corresponding RNA sequence.

22. (Twice Amended) The nucleic acid fragment of claim 21, said nucleotide sequence having~~, for at least one segment of 30 contiguous nucleotides,~~ at least 85% homology with a ~~segment of 30 contiguous nucleotides of the~~ second reference sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide ~~1825~~ 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein each segment of 30 contiguous nucleotides of said nucleotide sequence has at least 85% homology with a segment of 30 contiguous nucleotides of said second reference sequence.

23. (Twice Amended) ~~The~~ A synthetic or isolated nucleic acid fragment ~~of claim 21, said~~ that comprises a nucleotide sequence having~~, for at least one segment of 30 contiguous nucleotides,~~ at least 85% homology with a ~~segment of 30 contiguous nucleotides of the~~ reference sequence that is identical or fully complementary to a sequence starting at nucleotide 1266 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein each segment of 30 contiguous nucleotides of said nucleotide sequence has at least 85% homology with a segment of 30 contiguous nucleotides of said reference sequence.

24. (Twice Amended) The nucleic acid fragment of claim ~~21~~23, wherein said nucleotide sequence is identical or fully complementary to a ~~second nucleotide~~ sequence

starting at nucleotide 1266 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence.

32. (Amended) The reagent of claim 17, wherein said primer contains no more than ~~100~~ 30 nucleotides.

34. (Amended) The method of claim 20, wherein said primer contains no more than ~~100~~ 30 nucleotides.